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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,998	12/07/2000	Hilary A. Coller	2825.2006-001	3011

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EXAMINER
ANGELL, JON E

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/732,998	Applicant(s) COLLER ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) 1-12 and 21-35 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-35 are pending in the application.

Election/Restrictions

1. Applicant's election without traverse of Group III (claims 13-20) and species XXIV (EIF5A) in Paper No. 8 is acknowledged.

2. Claims 1-12 and 21-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g. see p. 18, line 16). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13, 15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Eilers et al. (EMBO J. Vol. 10, No. 1, pp. 133-141; 1991).

Eilers teaches a method for identifying an agent that regulated MYC-dependent transcriptional regulation of gene expression comprising the steps of:

a) obtaining an indicator cell that expresses a chimeric receptor comprising MYC and a ligand binding domain (here, a Rat1a cell expressing a MYC estrogen receptor (MYC-ER) chimera, see p. 133, second column and p. 138, Figure 6);

b) contacting the resulting indicator cell with an appropriate ligand in the presence and absence of an agent to be evaluated for its ability to regulate MYC's transcriptional regulation activity (here, in the presence and absence of the ligand estrogen in the presence in absence of MYC-ER, see p. 135, Figures 2 and 3);

c) isolating mRNA from a plurality of indicator cells (see p. 135, Figure 2);

d) comparing the level of gene expression in the indicator cells in the presence or absence of the agent (see p. 135, Figure 2)

such that if the effect of MYC on the expression of the gene is enhanced or inhibited in the presence and not the absence of the agent, then the agent regulates MYC-dependent transcriptional regulation of gene expression (here, gene expression is enhanced in the presence and not the absence of estrogen, e.g. see p. 135, Figure 2).

Eilers teaches that estrogen in the presence of MYC-ER activates MYC-dependent transcriptional regulation of gene expression (e.g. see p. 135, Figure 2).

Eilers also teaches that the level of gene expression is determined by Northern blot analysis (see, p. 135, Figure 2).

6. Claims 13, 14, 17 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (PNAS Vol. 94, pp. 12886-12891; 1997).

Lee teaches a method for identifying an agent that regulated MYC-dependent transcriptional regulation of gene expression comprising the steps of:

a) obtaining an indicator cell that expresses a chimeric receptor comprising MYC and a ligand binding domain (here, a Rat1a cell expressing a MYC-ER chimera or ΔMYC-ER chimera, see p.12889, first column and p. 12890, Figure 4);

b) contacting the resulting indicator cell with an appropriate ligand in the presence and absence of an agent to be evaluated for its ability to regulate MYC's transcriptional regulation activity (here, in the presence and absence of the ligand 4-hydroxytamoxifen (4-OHT) in the presence and absence of MYC-ER and ΔMYC-ER, see p.12889, first column and p. 12890, Figure 4);

c) isolating mRNA from a plurality of indicator cells (see p.12889, first column and p. 12890, Figure 4);

d) comparing the level of gene expression in the indicator cells in the presence or absence of the agent (see p.12889, first column and p. 12890, Figure 4)

such that if the effect of MYC on the expression of the gene is enhanced or inhibited in the presence and not the absence of the agent, then the agent regulates MYC-dependent transcriptional regulation of gene expression (here, gas1 gene expression is inhibited in the presence and not the absence of 4-OHT, and in the presence and not the absence of MYC-ER; e.g., see p.12889, first column and p. 12890, Figure 4).

Lee teaches that the ligand that induces the MYC chimeric receptor is 4-hydroxytamoxifen (e.g., see p.12889, first column and p. 12890, Figure 4).

Lee teaches that 4-OHT in the presence of MYC-ER inhibits MYC-dependent transcriptional regulation of gas1 gene expression (e.g., see p.12889, first column and p. 12890, Figure 4).

Lee also teaches that the level of gene expression is determined by Northern blot analysis (e.g., see p.12889, first column and p. 12890, Figure 4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eilers et al. (EMBO J. Vol. 10, No. 1, pp. 133-141; 1991) in view of Zhu et al. (PNAS Vol. 95, pp. 14470-14475; Nov. 1998).

Eilers teaches a method for identifying an agent that regulated MYC-dependent transcriptional regulation of gene expression comprising the steps of:

a) obtaining an indicator cell that expresses a chimeric receptor comprising MYC and a ligand binding domain (here, a Rat1a cell expressing a MYC estrogen receptor (MYC-ER) chimera, see p. 133, second column and p. 138, Figure 6);

b) contacting the resulting indicator cell with an appropriate ligand in the presence and absence of an agent to be evaluated for its ability to regulate MYC's transcriptional regulation activity (here, in the presence and absence of the ligand estrogen in the presence in absence of MYC-ER, see p. 135, Figures 2 and 3);

c) isolating mRNA from a plurality of indicator cells (see p. 135, Figure 2);

d) comparing the level of gene expression in the indicator cells in the presence or absence of the agent (see p. 135, Figure 2)

such that if the effect of MYC on the expression of the gene is enhanced or inhibited in the presence and not the absence of the agent, then the agent regulates MYC-dependent

transcriptional regulation of gene expression (here, gene expression is enhanced in the presence and not the absence of estrogen, e.g. see p. 135, Figure 2).

Eilers also teaches that the agent is evaluated in the presence of cyclohexamide (see, p. 137, second column and p. 138, Figure 6).

Eilers does not teach that the gene whose level of expression is being monitored is EIF5A, or that the level of gene expression is determined by hybridization to an oligonucleotide microarray.

Zhu teaches that gene expression in cells can be monitored using an oligonucleotide microarray, and specifically teaches that EIF5A gene expression can be monitored by hybridization to the oligonucleotide microarray (seep. 14470, under "Sample Preparation and Analysis with DNA Arrays"; and p. 14472, second column, Table 1 under "Translation factors").

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time of invention to combine the method of Eilers with the assay of Zhu to create a method that utilizes a cell expressing a MYC-ER chimera and estrogen to enhance (and inhibit) MYC-dependent transcriptional regulation of gene expression, and to assay the resulting effect on gene expression using a microarray, wherein the gene whose level of expression is being evaluated for regulation is EIF5A.

The motivation to combine the teachings of Eilers with Zhu is evidenced by the Eilers' teaching that transcriptional gene regulation can be monitored by evaluating the mRNA levels

(e.g., see, p. 135, Figure 2), and Zhu's teaching that, "DNA array assay is performed easily and can detect subtle changes in mRNA levels" (see p. 14470, first column). Furthermore, Zhu teaches an oligonucleotide microarray that can be used to monitor the expression level of EIF5a (see p. 14472, second column, Table 1 under "Translation factors"). Therefore evaluating gene expression using the oligonucleotide microarray taught by Zhu would necessarily evaluate the level of EIF5A gene expression.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

J. Eric Angell
June 16, 2002